

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS") and the TRICARE Management Activity ("TMA") (collectively "the United States"); Keith Schenker and DJ PARTNERSHIP 2011, LLP (collectively, "Relators"); and ISTA Pharmaceuticals, Inc. ("ISTA"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. ISTA Pharmaceuticals, Inc. ("ISTA") is a Delaware corporation headquartered in Irvine, California. ISTA has developed, distributed, marketed, and sold pharmaceutical products in the United States, including the drug sold under the trade name Xibrom®. In June 2012, ISTA became a wholly-owned subsidiary of Bausch & Lomb, Incorporated.

B. Relators have filed the following qui tam actions against ISTA captioned as follows (collectively the "Civil Actions"):

- (i) United States ex rel. Keith Schenker v. ISTA Pharmaceuticals, Inc., Case No. 07-CV-0372 (C) (W.D.N.Y.);
- (ii) United States, et al., ex rel. DJ PARTNERSHIP 2011, LLP v. ISTA Pharmaceuticals, Inc., Case No. 11-cv-0367 (A) (W.D.N.Y.)

C. On such date as may be determined by the Court, ISTA will plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Criminal Plea") to an Information to be filed in United States v. ISTA Pharmaceuticals, Inc., Criminal Action No. 13-CR-99A (W.D.N.Y.) (the "Criminal Action") that will allege that: (1) ISTA conspired to

introduce a misbranded drug, Xibrom, in interstate commerce with intent to defraud or mislead in violation of 18 U.S.C. § 371, 21 U.S.C. §§ 331(a), 352(f)(1) and 333(a)(2); and (2) ISTA conspired to knowingly and willfully offer or pay remuneration directly or indirectly, overtly or covertly, in cash or in kind to persons to induce such persons to prescribe Xibrom, a drug for which payment was made in whole or in part under a Federal health care program, in violation of 18 U.S.C. § 371 and 42 U.S.C. § 1320A-7B(b)(2)(B).

D. ISTA has entered or will be entering into separate settlement agreements, described in Paragraph 1.b., below (hereinafter referred to as the “Medicaid State Settlement Agreements”), with certain states and the District of Columbia in settlement of the Covered Conduct. States with which ISTA executes a Medicaid State Settlement Agreement in the form to which ISTA and the National Association of Medicaid Fraud Control Units (“NAMFCU”) Negotiating Team have agreed, or in a form otherwise agreed to by ISTA and an individual State, shall be defined as “Medicaid Participating States.”

E. The United States alleges that ISTA caused claims for payment for Xibrom® to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C §§ 1395-1395kkk (“Medicare”), and to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396W-5 (“Medicaid”). The United States further alleges that ISTA caused claims for payment for Xibrom® to be submitted to the TRICARE program, 10 U.S.C. §§ 1071-1110b (“TRICARE”).

F. The United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 3, below, against ISTA for engaging

in the following conduct during the period January 1, 2006 through March 31, 2011

(hereinafter referred to as the "Covered Conduct"):

(1) ISTA knowingly promoted the sale and use of Xibrom® for the following uses for which Xibrom® had not been approved as safe and effective by the United States Food and Drug Administration ("FDA"): treatment of cystoid macular edema ("CME"), prevention of CME, treatment of pain and inflammation associated with non-cataract eye surgery, treatment of glaucoma, and treatment of inflammation (other than postoperative inflammation). Certain of these uses were not medically-accepted indications as defined by 42 U.S.C. § 1396r-8(k)(6), and were not covered by Medicare, TRICARE, or state Medicaid programs. (2) ISTA knowingly offered and paid illegal remuneration to certain ophthalmologists and optometrists to induce them to prescribe Xibrom®, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

As a result of the foregoing conduct, the Government alleges that ISTA knowingly caused false or fraudulent claims for Xibrom® to be submitted to, or caused purchases by, Medicare, Medicaid, and TRICARE.

G. The United States also contends that it has certain administrative claims against ISTA for engaging in the Covered Conduct.

H. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement. Relators also claim entitlement to reasonable expenses, attorneys' fees and costs, and ISTA and Relators have entered into, or will be entering into, separate agreements to resolve these claims.

I. This Agreement is made in compromise of disputed claims. This Settlement Agreement is neither an admission of liability by ISTA nor a concession by the United States that its claims are not well founded. With the exception of the specific conduct for which ISTA is pleading guilty as described in the Plea Agreement filed in connection with the Criminal Action, ISTA expressly denies the allegations of the United

States and the Relators as set forth herein and in the Civil Actions and denies that it has engaged in any wrongful conduct in connection with the Covered Conduct.

J. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. ISTA shall pay to the United States and the Medicaid Participating States collectively the sum of fifteen million dollars (\$15,000,000.00), plus interest at the rate of 1.375% per annum from November 7, 2012, and continuing until and including the date of payment (the "Settlement Amount") under the terms and conditions set forth in this Agreement. The Settlement Amount shall constitute a debt immediately due and owing to the United States and Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States as follows:

(a) ISTA shall pay to the United States the sum of \$14,609,746.16, plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than ten (10) business days after (i) this Agreement is fully executed by the Parties and delivered to ISTA's attorneys; or (ii) the

Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.

(b) ISTA shall pay the Medicaid Participating States the sum of \$390,253.84, plus accrued interest as set forth above, to be disbursed in accordance with written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the agreements that ISTA will enter into with the Medicaid Participating States.

(c) If ISTA's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or ISTA. If either the United States or ISTA exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, ISTA will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims, actions or proceedings arising from the Covered Conduct that are brought by the United States within 90 calendar days of rescission, except to the extent such defenses were available on the day on which the qui tam complaints listed in Preamble Paragraph B, above, were filed.

2. Contingent upon the United States receiving the Federal Settlement Amount from ISTA, the United States agrees to pay Keith Schenker, as soon as feasible upon receipt, the sum of \$2,556,705.58 ("Relator's Share"), as Relator's share of the

proceeds pursuant to 31 U.S.C. § 3730(d). No other relator payments shall be made by the United States with respect to the matters covered by this Agreement. Relators Schenker and DJ Partnership represent that they will abide by the terms of any written and executed separate agreements that they may have entered into with each other concerning the allocation of the Relator Share among themselves.

3. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of ISTA set forth in this Agreement, and conditioned upon ISTA's full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release ISTA, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees and assigns and their current and former directors, officers, employees, and agents individually and collectively, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, Section 0.45 (d); or the common law theories of fraud, payment by mistake, unjust enrichment, disgorgement of illegal profits, and, if applicable, breach of contract.

4. Subject to the exceptions in Paragraph 6 (concerning excluded claims), below, in consideration of the obligations of ISTA set forth in this Agreement, conditioned upon ISTA's full payment of both the Settlement Amount and Relators'

reasonable attorneys' fees, Relators, for themselves and for their partners, heirs, successors, transferees, attorneys, agents, and assigns, agree to dismiss with prejudice any currently pending claims against ISTA and release ISTA, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees and assigns and their current and former directors, officers, employees, agents, servants, representatives, attorneys, consultants, successors, heirs, executors, administrators, and assigns, individually and collectively, from any and all liability, claims, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation or that they otherwise would have standing to bring, including, but not limited to, liability to Relators arising from any claim the Relators have, may have, or could have asserted on behalf of the United States under the False Claims Act and on behalf of any states under any state false claims acts.

5. Simultaneously with this Agreement, ISTA is entering into a Divestiture Agreement with HHS-OIG that addresses HHS-OIG's exclusion authority.

6. Notwithstanding the releases given in paragraphs 3 through 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability except as set forth in the Plea Agreement resolving the Criminal Action;

- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
- i. Any liability of individuals (including current or former directors, officers, employees, agents, or shareholders of ISTA) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted or charged, are convicted, or who enter into a plea agreement, related to the Covered Conduct.

7. Relators and their partners, heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator Schenker's receipt of the payment described in Paragraph 2, Relators Schenker and DJ Partnership and their partners, heirs, successors,

attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

8. ISTA waives and shall not assert any defenses ISTA may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. ISTA fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that ISTA has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. In consideration of the obligations of Relators set forth in this Agreement, ISTA for itself and for its partners, heirs, successors, transferees, attorneys, agents and assigns, releases Relators from any and all liability, claims, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in

contract or in tort, under any federal or state statute or regulation or at common law or that it otherwise would have standing to bring against Relators.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier), TMA, or any state payer, related to the Covered Conduct; and ISTA agrees not to resubmit to any Medicare contractor, TMA, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

12. ISTA agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of ISTA, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related Plea Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) ISTA's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s)

in connection with the matters covered by this Agreement (including attorneys' fees);

- (4) the negotiation and performance of this Agreement and any Plea Agreement; and
- (5) the payment ISTA makes to the United States pursuant to this Agreement and any payments that ISTA may make to Relators, including costs and attorneys' fees,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by ISTA, and ISTA shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by ISTA or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: ISTA further agrees that, within 90 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any

State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by ISTA or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. ISTA agrees that the United States, at a minimum, shall be entitled to recoup from ISTA any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by ISTA or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on ISTA or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine ISTA's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. ISTA agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Specifically, upon reasonable notice, ISTA shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available,

and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. ISTA further agrees to furnish to the United States, upon request, complete and unredacted copies of all relevant, non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 15 (waiver for beneficiaries paragraph), below.

15. ISTA agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as Covered Conduct.

16. Upon the Effective Date of this Agreement, the United States shall file Notices of Intervention in Part and Declination in Part in the Civil Actions, as follows:

- (a) The United States shall intervene in the Civil Actions as to the Covered Conduct only; and
- (b) The United States shall decline as to all other allegations set forth in the Civil Actions.

17. Upon receipt of the payment described in Paragraph 1, above, the United States and Relators shall promptly sign and file Joint Notices of Dismissal of the Civil Actions pursuant to Rule 41(a)(1). The Notices of Dismissal shall be with prejudice as to

the United States' and Relators' claims as to the Covered Conduct, and the Notices of Dismissal shall be without prejudice to the United States and with prejudice as to Relators as to all other claims.

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

20. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Western District of New York. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

21. This Agreement constitutes the complete agreement between the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

22. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

24. This Agreement is binding on ISTA's successors, transferees, heirs, and assigns.

25. This Agreement is binding on Relators' successors, transferees, partners, heirs, and assigns.

26. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

27. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 5/22/13

BY: *Colin M. Huntley*
COLIN M. HUNTLEY
BENJAMIN S. YOUNG
Trial Attorneys
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 5/22/13

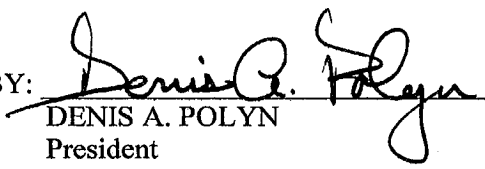
BY: *Kathleen A. Lynch*
KATHLEEN A. LYNCH
Assistant United States Attorney
Western District of New York

DATED: 5/21/13

BY: *Robert K. DeConti*
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of
Health and Human Services

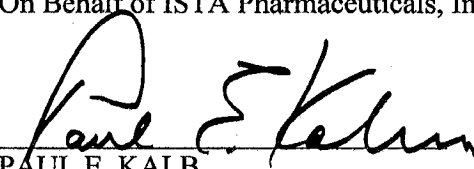
ISTA PHARMACEUTICALS, INC.

DATED: 5/20/13

BY: 
DENIS A. POLYN
President
ISTA Pharmaceuticals, Inc.

On Behalf of ISTA Pharmaceuticals, Inc.

DATED: 5/22/13

BY: 
PAUL E. KALB
KRISTIN GRAHAM KOEHLER
Sidley Austin LLP

ALICE S. FISHER
Latham & Watkins LLP

Counsel for ISTA Pharmaceuticals, Inc.

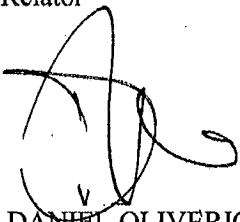
RELATOR KEITH SCHENKER

DATED: 5/15/13

BY: 
KEITH SCHENKER

Relator

DATED: 5/19/13

BY: 
DANIEL OLIVERIO
Hodgson Russ, LLP

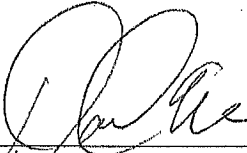
Counsel for Relator Keith Schenk

RELATOR DJ PARTNERSHIP 2011 LLP

DATED: _____

5/15/13

BY: _____

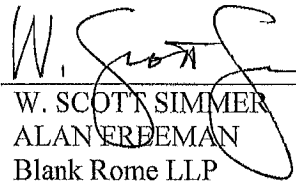

DAVID FARBER,
Individually and on Behalf of
DJ PARTNERSHIP 2011 LLP

Relator

DATED: _____

5/16/2013

BY: _____


W. SCOTT SIMMER
ALAN FREEMAN
Blank Rome LLP

Counsel for Relator DJ Partnership 2011 LLP